

COVID-19 Vaccination Plan

TENNESSEE

Tennessee Department of Health
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Section 1: COVID-19 Vaccination Preparedness Planning

A. Describe your early COVID-19 vaccination program planning activities, including lessons learned and improvements made from the 2009 H1N1 vaccination campaign, seasonal influenza campaigns, and other responses to identify gaps in preparedness.

- a. The TDH Communicable and Environmental Disease and Emergency Preparedness (CEDEP) division served as lead for the 2009 H1N1 Influenza Pandemic Outbreak response in Tennessee. TDH CEDEP response activities included establishing command and control, defining communication pathways, refining surveillance and epidemiology, revisiting fatality management, expanding laboratory services, coordination of mass vaccination clinics through local, regional, and metropolitan health departments, hiring of temporary staff, vaccine distribution, tracking doses administered, warehousing and distribution of medical countermeasures, deployment of personal protective equipment (PPE), processing contracts (including the state's influenza call center and provision of immunization services to agencies targeting underserved populations), and development of mass media messaging and guidance. There were lessons learned and best practices identified from this response that generated numerous opportunities for TDH staff to deliver abstracts, posters, presentations, and articles. Early vaccine planning activities and lessons learned included:
 - Engaging federal officials from CDC, HHS ASPR, and other Region IV states in a gap analysis discussion pertaining to where the federal response ends and the state and local response begins.
 - Identification of ancillary supplies (needles, syringes, sharps containers, etc.) needed to mount a massive vaccination response as was most recently experienced through our multi-year statewide response to hepatitis A and 2009 H1N1 response.
 - Identification of both fixed and mobile cold chain capacity (vaccine refrigerators, mobile coolers, fridge freeze units, temperature data loggers, etc.) to store vaccine both centrally and allow for mobile vaccination operations in the community as was most recently experienced through our multi-year statewide response to hepatitis A and 2009 H1N1 response.
 - Identification of external stakeholders with vaccination response expertise to best inform resource allocation decisions and public messaging strategies.
 - Identification of surge contract staffing needs for almost every aspect of the vaccination response including clerical, administrative, clinical, epidemiology, and information technology as was most recently experienced through our multi-year statewide response to hepatitis A and 2009 H1N1 response.
 - Identification of essential elements of information and response metrics that will be needed to inform the public and local, state, and federal leadership on a regular basis through situation reporting, data visualization, and dashboarding.

- Identification of immunization information system enhancements and a multi-tier cohort of knowledgeable staff that can operate all aspects of vaccine systems response from provider enrollment, validation, vaccine allocation, reporting, and technical assistance.
 - Conduct outreach to vulnerable populations through non-profit entities and update GIS mapping of known vulnerable populations to target vaccine interventions.
 - Identification of proactive administrative preparedness steps and removal of barriers that can be taken to expedite procurement, contracting, and allocation of grant dollars to sub-recipients.
- b. The TDH Vaccine-Preventable Diseases and Immunization Program (VPDIP) worked closely with the Emergency Preparedness Program to respond to the hepatitis A outbreak from December 2017-May 2020, involving more than 3,000 cases. Experience gained and gaps identified included:
- TDH Incident Command System was activated and provided a sustained, coordinated response for 18 months.
 - Local health departments were tasked to complete case interviews, perform contact tracing and monitoring, and provide individual and public communications and needed to reassign duties to meet the demands of that outbreak response.
 - Vaccination strike teams were deployed across the state to reach vulnerable populations at risk of contracting and spreading the virus. More than 23,000 doses of hepatitis A vaccine were provided by six strike teams and nearly 233,000 doses were administered by private and public health providers in medical offices, health departments, jails, prisons, drug rehabilitation centers, medically-assisted opioid treatment programs, homeless shelters and encampments, and other locations where those not routinely seeking healthcare could be reached. These strike teams proved to be a best practice for the successful administration of vaccines to at-risk populations.
 - Challenges included individual concerns regarding the vaccine itself and mistrust of the government, the hiring and supervision of large numbers of contracted workers, coordination of efforts and communication with metro jurisdictions that are not under the umbrella of TDH, and the need for sustained public communication around this prolonged outbreak.

B. Include the number/dates of and qualitative information on planned workshops or tabletop, functional, or full-scale exercises that will be held prior to COVID-19 vaccine availability. Explain how continuous quality improvement occurs/will occur during the exercises and implementation of the COVID-19 Vaccination Program.

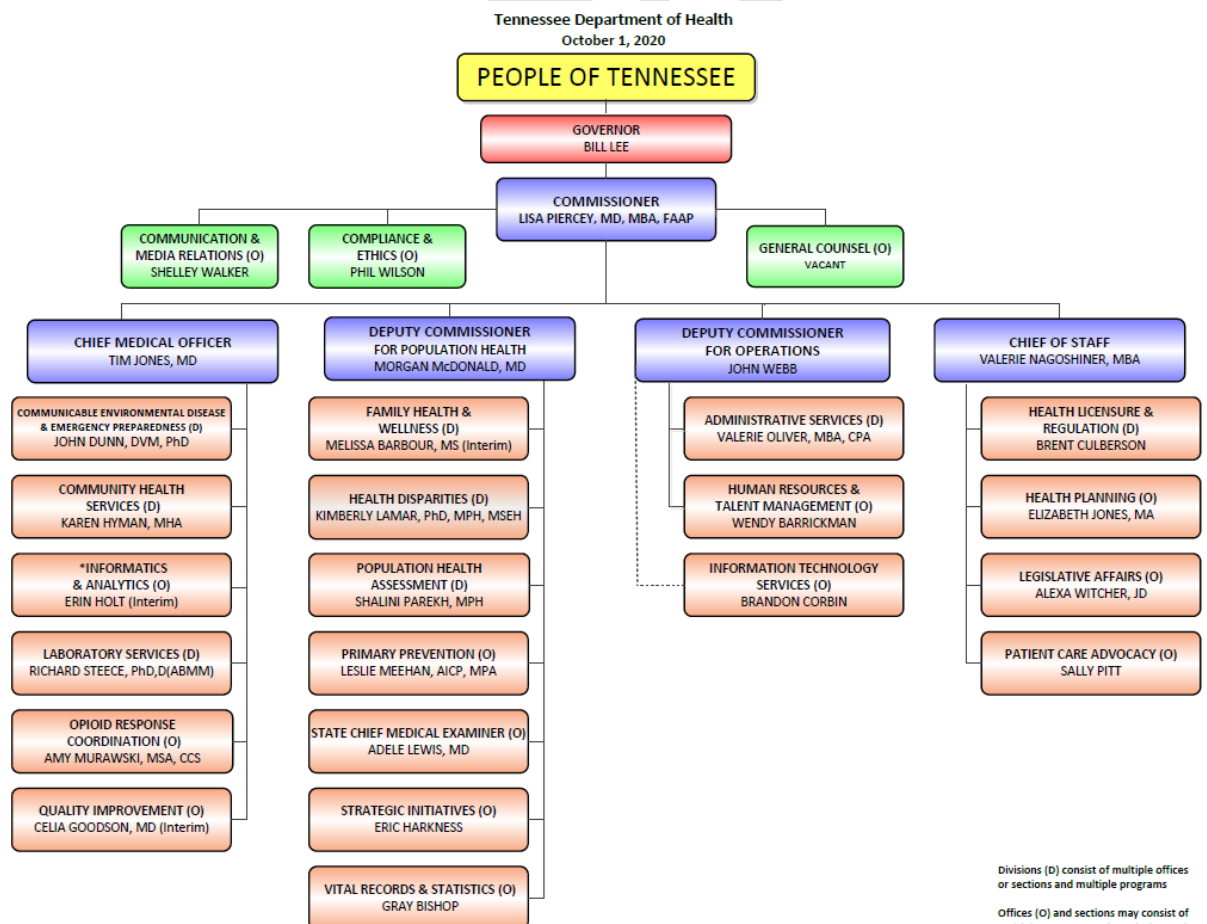
- a. With the support of executive leadership in 2018 the Tennessee Department of Health initiated a statewide pandemic preparedness vaccination effort known as Fight Flu TN. The goal of the effort was to empower each of our 95 counties to build robust and trusted community partnerships, vaccination plans, trained staff, and ability to operate autonomously in the face of worldwide pandemic. This was coupled with the interest of improving vaccination rates and the need to innovate vaccination administration strategies.
 - On Dec. 5, 2018, TDH stood up 115 Points of Dispensing (PODs), 113 that were open to the public (of those 84 were walk-through on site, 21 walk-through off site, and 8 drive through) and 2 closed PODs for special populations and a total of nearly 4,500 vaccines were administered in one day across the 95 counties. In total over 1,200 staff were involved in the response efforts which included not only the vaccination PODs but also 14 Health Emergency Operations Centers at the state and local level. Statewide after action reporting and improvement plans were developed with continuous quality improvement in mind.
 - On Nov. 19, 2019, TDH increased the number of simultaneously opened PODs from 115 to 175, including 156 open PODs (of those 56 were walk-through on site, 75 walk-through off site, and 25 drive through) and 19 closed PODs for special populations (of those 15 were for vulnerable populations and 4 for first responders), and the number of administered doses of flu vaccine doubled to 9,666. Statewide after action reporting and improvement plans were developed with continuous quality improvement in mind. Additionally, vaccines administered during Fight Flu TN were recorded manually into TennIIS (Tennessee Immunization Information System) after the conclusion of the event.
 - On Nov. 19, 2020, TDH will again activate our public health infrastructure in all 95 counties to Fight Flu TN. All our local health departments have already developed plans that have been tailored to accommodate the realities of our current COVID-19 response. In addition, community healthcare partners, universities, and others will be engaged in this one day preparedness event that will move the needle on COVID-19 vaccine preparedness. This year's exercise will also incorporate real-time reporting of administered doses of vaccine into TennIIS through a new Mass Immunizations Module, which will allow for the rapid entering of vaccine administration data during mass immunization events.

- b. In collaboration with the Tennessee Emergency Management Agency (TEMA), TDH is creating a series of web-based vaccination table-top exercises which will be conducted across the state in partnership with our Emergency Preparedness and Response Healthcare Coalitions (HCCs). The focus of the exercises will include vaccine assumptions, logistics, administration, and reporting and these exercises will be used to educate those involved with vaccinating individuals through hospitals, employee health, schools, institutes of higher education, and other partnering organizations. Initial table-top exercise materials are in draft and the first three exercises are scheduled for October 21-23, 2020, with additional sessions to be scheduled as interest dictates.

Section 2: COVID-19 Organizational Structure and Partner Involvement

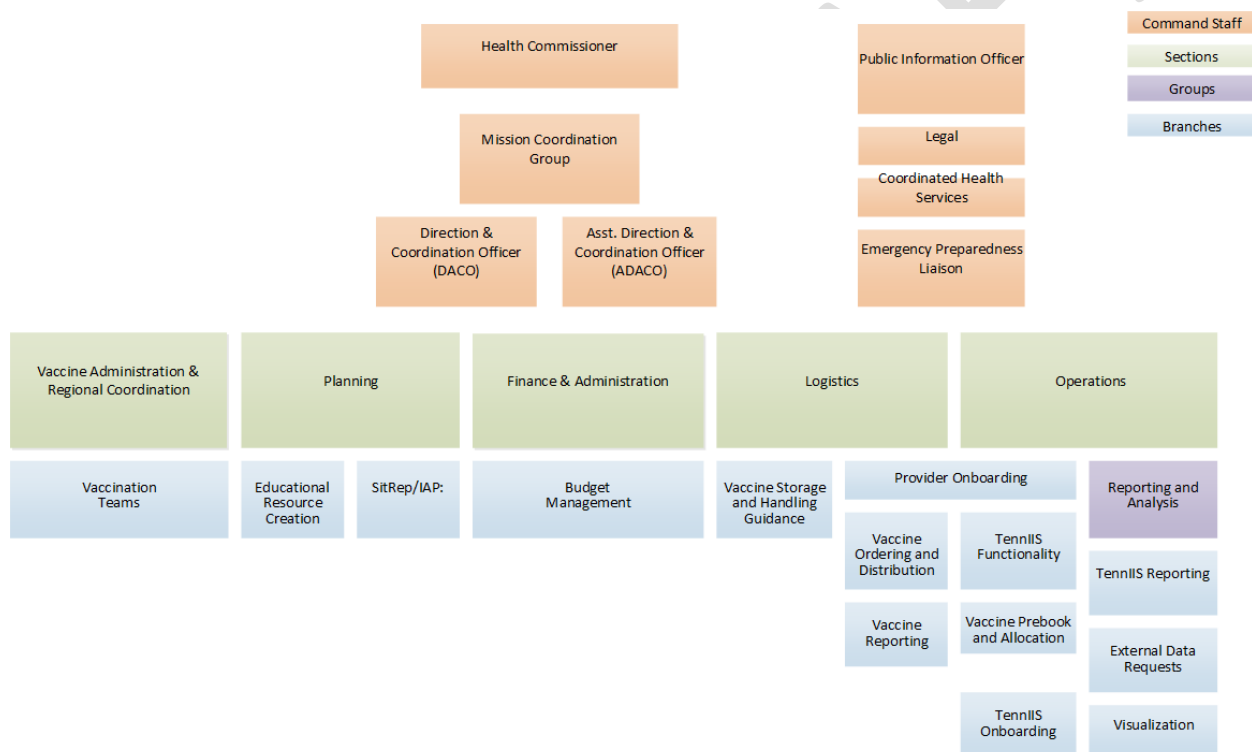
Describe your organizational structure.

The Tennessee Department of Health is led by Dr. Lisa Piercey, Commissioner of Health, who reports directly to Governor Bill Lee. The TDH Executive Leadership Team consists of the Chief of Staff, the State Chief Medical Officer, Deputy Commissioner for Population Health, and the Deputy Commissioner for Operations.



Describe how your jurisdiction will plan for, develop, and assemble an internal COVID-19 Vaccination Program planning and coordination team that includes persons with a wide array of expertise as well as backup representatives to ensure coverage.

The initial TDH COVID-19 Vaccination Program Planning Team included members of the Vaccine-Preventable Diseases and Immunization Program team and the Office of Emergency Preparedness. Two of the representatives were with state departments of health during the 2009 H1N1 pandemic. This team began meeting in late June 2020. In late July 2020, leadership of Community Health Services, which oversees the 89 rural health departments, was added, as well as a representative of our overall COVID-19 EP Response team and the TDH Office of Communications and Media Relations. There is enough redundancy of expertise within the planning and coordination team to ensure coverage in the event of a lead member's inability to continue in their role.



Describe how your jurisdiction will plan for, develop, and assemble a broader committee of key internal leaders and external partners to assist with implementing the program, reaching critical populations, and developing crisis and risk communication messaging.

TDH has convened a Pandemic Vaccine Planning Stakeholder group which meets every two weeks and is leveraged to help inform allocation decisions, define priority populations, and identify gaps in knowledge. The group is comprised of more than 28 different offices, agencies, and departments representing public health, rural health, refugee and other minority populations, legislators, experts in bioethics, medical societies, communications experts, health care coalitions, emergency management, and others. This group will also be used to vet crisis and risk communication messages. In addition, the Unified Command Group (UCG) and the

Governor's office are highly engaged in any public communications or messaging campaigns addressing vaccinations

Identify and list members and relevant expertise of the internal team and the internal/external committee.

Internal Team:

Leads: TDH Vaccine-Preventable Diseases and Immunization Program (VPDIP); TDH Emergency Preparedness Program; Two members of the team were employed with departments of health during the H1N1 pandemic and all but one of the team members held principal roles during Tennessee's hepatitis A epidemic response.

Members: TDH Office of Communications and Media Relations, TDH Office of Community Health Services, TDH Emergency Preparedness Program

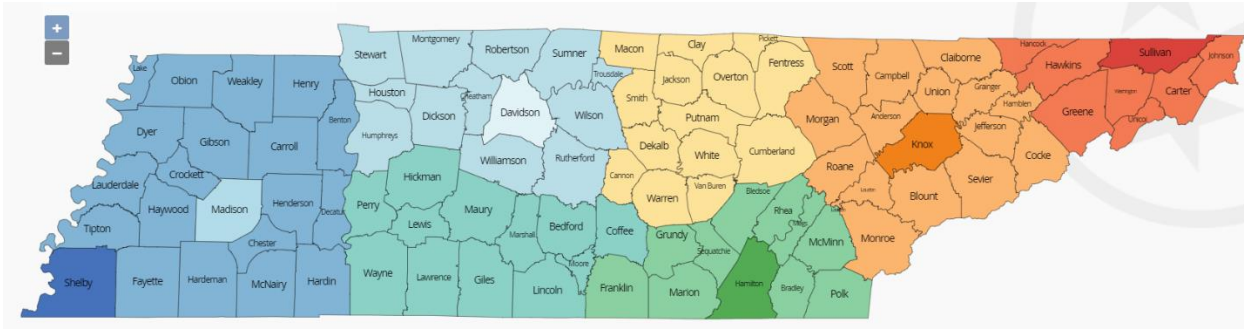
Stakeholder Group (external team):

Leads: TDH Vaccine-Preventable Diseases and Immunization Program (VPDIP); TDH Emergency Preparedness Program

Members: TDH Vaccine-Preventable Diseases and Immunization, Emergency Preparedness, and Community Health Services programs; TDH COVID-19 Emergency Response Team; TDH Office of Disparities Elimination; TDH Office of Communications and Media; Metro Health Departments (4 of 6 participating); TN Pharmacists' Association; TN Chapter of the American Academy of Pediatrics; TN Hospital Association; TN Primary Care Association; TN Department of Corrections; TN Sheriffs' Association; Vanderbilt Center for Biomedical Ethics and Society; TN Higher Education Commission; TN Commission on Aging and Disabilities; TN Home Care Association; Bureau of TennCare (state Medicaid agency); Tennessee Emergency Management Agency; TN Department of Education, Office of Child Health; TN Medical Association; Tennessee legislators; Tennessee Office of Refugees; Tennessee Health Care Coalitions; TN Department of Intellectual and Developmental Disabilities, TN Academy of Family Physicians.

Describe how your jurisdiction will coordinate efforts between state, local, and territorial authorities.

Tennessee is a hybrid state where 89 of its 95 counties report to the State and six metros are independent from the State. Tennessee contracts with these six counties (Shelby, Madison, Davidson, Sullivan, Knox, and Hamilton) to conduct public health activities.



Tennessee does not have territorial authorities. Statewide efforts are coordinated through multiple agencies involved with the State's overall pandemic response and communicated through agency leadership, the Unified Command Group (UCG), and the Governor's office. Coordination between the State and local authorities occurs through numerous channels, including partnering agencies, medical societies, health care coalitions, and emergency management agencies, in addition to multiple opportunities for partners to participate in calls and webinars (bi-weekly COVID-19 update webinar for clinicians, bi-weekly calls between TDH and metro, regional and local health departments, monthly calls with Tennessee Hospital Association, long term care facilities, and others, bi-weekly press conferences that include the Commissioner of Health, and others).

Describe how your jurisdiction will engage and coordinate efforts with leadership from tribal communities, tribal health organizations, and urban Indian organizations.

Tennessee does not have federally-recognized tribal communities.

List key partners for critical populations that you plan to engage and briefly describe how you plan to engage them, including but not limited to:

- *Pharmacies*
- *Correctional facilities/vendors*
- *Homeless shelters*
- *Community-based organizations*

Critical populations will be engaged through the following partners, largely through our Stakeholder Group and professional societies. These include the following:

Pharmacies—through our partnership with TN Pharmacists' Association we are engaging pharmacies, especially those in rural areas, to complete the CDC Provider Agreement and Profile and onboarding process to become pandemic vaccine providers in their communities.

Correctional facilities—through our partnership within the Stakeholder Group, TN Department of Corrections and the TN Sheriffs' Association are part of the planning process for vaccine allocations and distribution to ensure the population housed in correctional facilities is included in planning. Plans are underway to onboard the prison intake facilities to provide COVID-19 vaccine as they have similarly done with hepatitis A vaccine. Additionally, vaccination strike teams will be scheduled to visit jails and other congregate care facilities to ensure these populations are provided the opportunity to receive vaccine. During the hepatitis A outbreak,

strike teams delivered hepatitis A vaccine in all county jails across the state at least once, if not on a recurring basis. We will leverage this model and the relationships built by local public health to implement the same vaccination outreach.

Homeless shelters—through our partnership with the TDH Office of Disparities Elimination, strike teams will be scheduled to visit locations where individuals experiencing homelessness gather. During the hepatitis A outbreak, strike teams prioritized homeless shelters as one of the target sites for providing vaccine outreach. We will leverage the relationships built by our local public health during this response.

Community-based organizations—through our multiple partner agencies, community health centers, federally-qualified health centers, hospitals, home health agencies, K-12 schools, institutes of higher education, large corporations, urgent visit clinics, and private medical providers are being contacted to on-board as pandemic vaccine providers.

Section 3: Phased Approach to COVID-19 Vaccination

A. Describe how your jurisdiction will structure the COVID-19 Vaccination Program around the three phases of vaccine administration:

Phase 1: Potentially Limited Doses Available

Phase 2: Large Number of Doses Available, Supply Likely to Meet Demand

Phase 3: Likely Sufficient Supply, Slowing Demand

After careful review of the CDC Playbook and the National Academies' of Sciences, Engineering and Medicine's Framework for Equitable Allocation of COVID-19 Vaccine and discussion with the Stakeholder Group, TDH leadership, and the Unified Command Group, the following structure has been adopted for the allocation and prioritization of COVID-19 vaccines:

Allocation:

Ten percent of the State's allocation of COVID-19 vaccines will be reserved by the State for use in targeted areas with high Social Vulnerability Index (SVI) values.

Five percent of the State's allocation of COVID-19 vaccines will be distributed equitably among all 95 counties.

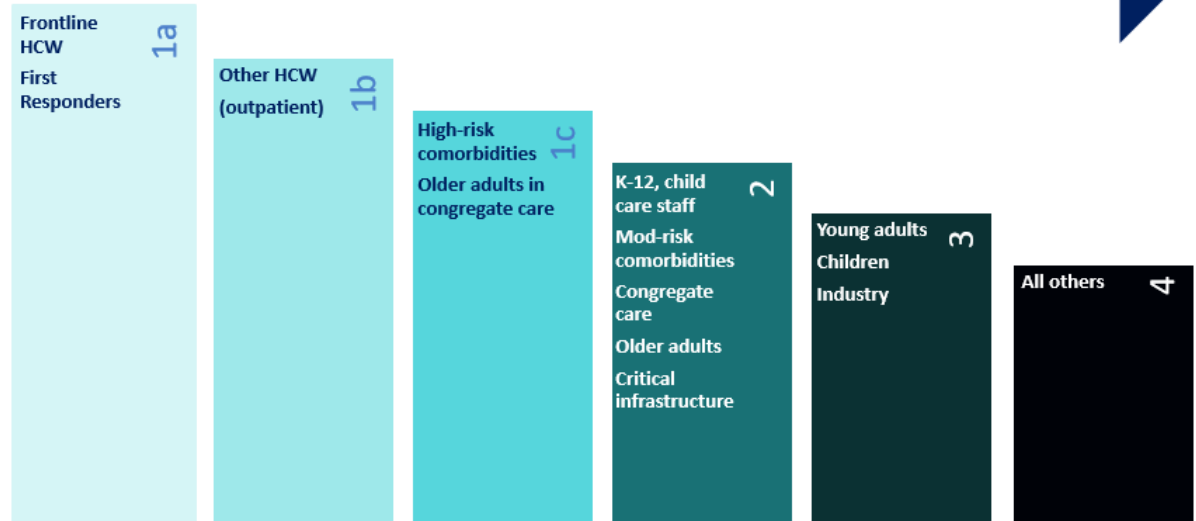
Eighty-five percent of the State's allocation of COVID-19 vaccines will be distributed among all 95 counties based upon their populations.

As vaccine becomes available, populations will be prioritized based upon risk of contracting and spreading the virus, as well as their risk of morbidity and mortality from COVID-19. Tennessee plans four allocation phases, based upon risk and informed by the NASEM's Framework. These phases are as follows:

Vaccine Allocation Phases

Equity is a crosscutting consideration:

In each population group, vaccine access should be prioritized for geographic areas identified through CDC's Social Vulnerability Index or another more specific index.



Adapted from <https://www.nap.edu/catalog/25917/framework-for-equitable-allocation-of-covid-19-vaccine>

Additionally, phases will be sub-prioritized, with individuals in each population who have conditions or circumstances that place them at significant risk for poor outcomes given first opportunity to receive vaccine.

It is anticipated that vaccine availability will increase substantially, allowing rapid movement from Phase 2 to Phases 3 and 4 (or making these phases obsolete).

Section 4: Critical Populations

A. Describe how your jurisdiction plans to: 1) identify, 2) estimate numbers of, and 3) locate (e.g., via mapping) critical populations. Critical population groups may include:

TDH plans to use Geographic Information System (GIS) mapping and Tiberius functionality to locate/map all critical populations.

- *Healthcare personnel*—Data obtained from the Bureau of Labor Statistics, Occupational Employment Statistics May 2019 and by health care facility direct reporting.
- *Other essential workers*—Data obtained from the Bureau of Labor Statistics, Occupational Employment Statistics May 2019.
- *Long-term care facility residents (e.g., nursing home and assisted living facility residents)*
-- Data obtained from the CDC Tiberius Database and the Tennessee State Licensure Database.

- *People with underlying medical conditions who are risk factors for severe COVID-19 illness*-- Data obtained from Tennessee Office of Vital Records and Statistics and the Tennessee Behavioral Risk Factor Surveillance System.
- *People 65 years of age and older*—Data obtained from Tennessee Office of Vital Records and Statistics and CDC Tiberius Database.
- *People from racial and ethnic minority groups*—Data obtained from Tennessee Office of Vital Records and Statistics, US Census Bureau, and CDC Tiberius Database.
- *People from tribal communities*—TN has no federally-recognized tribal communities
- *People who are incarcerated/detained in correctional facilities*—data obtained from the TN Department of Corrections and the TN Sheriffs' Association county jail census September 2020.
- *People experiencing homelessness/living in shelters*—National Coalition for the Homeless (state-level data).
- *People attending colleges/universities*-- Data obtained from Tennessee Higher Education Commission.
- *People living and working in other congregate settings*-- Data obtained from Tennessee Departments of Correction, Mental Health and Substance Abuse Services, Child Services, and Corrections.
- *People living in rural communities*—Data obtained from U.S. Department of Agriculture, Economic Research Services (ERS) 2013 Urban Influence Codes (UIC).
- *People with disabilities*—data obtained from the CDC's Social Vulnerability Index and the TN Department of Intellectual and Developmental Disabilities.
- *People who are under- or uninsured*— Data obtained from US Census, CDC's Social Vulnerability Index.

B. *Describe how your jurisdiction will define and estimate numbers of persons in the critical infrastructure workforce, which will vary by jurisdiction.*

Tennessee defines critical infrastructure workforce (excluding health care workers) as those working in food and beverage supply, public transportation, construction, transportation of goods, utilities and the postal service. Estimates are obtained through the Department of Labor and Workforce. The State's Economic Recovery Group (ERG) will assist in identifying corporations that serve in critical infrastructure capacities.

C. *Describe how your jurisdiction will determine additional subset groups of critical populations if there is insufficient vaccine supply.*

Tennessee will further stratify critical populations by prioritizing those with comorbid conditions or situations placing them at increased risk for poor outcomes from COVID-19.

D. *Describe how your jurisdiction will establish points of contact (POCs) and communication methods for organizations, employers, or communities (as appropriate) within the critical population groups*

The State's Economic Recovery Group (ERG) has agreed to assist the Program by making first contact with leaders within critical infrastructure employers and large corporations so that these

entities may serve as a conduit for communications to their employees. Additionally, the members of the Stakeholder Group will serve as a resource for connecting with critical populations and connecting them with opportunities for vaccination.

Section 5: COVID-19 Provider Recruitment and Enrollment

A. *Describe how your jurisdiction is currently recruiting or will recruit and enroll COVID-19 vaccination providers and the types of settings to be utilized in the COVID-19 Vaccination Program for each of the previously described phases of vaccine availability, including the process to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.*

VPDIP developed a survey to gauge the interest of facilities in becoming pandemic vaccinating providers. This survey was deployed on April 6, 2020 to all licensed physicians and pharmacists in Tennessee and the full TennNIS provider list including pharmacies and urgent care sites. This survey assessed for the facilities':

- Interest in becoming a pandemic provider
- Provider type
- Patient population
- Storage capacity
- Number of staff
- Storage and handling information

From the list of >1000 respondents, VPDIP started approving facilities' storage units and verifying their status in TennNIS.

Once the Provider Agreement (PA) was released by CDC, the survey was updated to mirror the document. Surveys were then resent to respondents with information already completed to the points of contact for hospitals in Phase 1A. All elements of the PA can be completed within the survey; however, facilities are also able to complete the fillable PDF and VPDIP staff will enter the information into the database for the facility.

Tennessee will continue this process for all hospitals and then start onboarding local and regional pharmacy partners not working through CDC.

B. *Describe how your jurisdiction will determine the provider types and settings that will administer the first available COVID-19 vaccine doses to the critical population groups listed in Section 4.*

VPDIP's first priority is to enroll hospitals with emergency departments and intensive care units that would see the highest acuity patients. Enrollment will then expand to include all hospitals in the state, so that they may provide vaccine to qualifying staff. Our next priority is to ensure all health departments have completed the PA and are ready to receive vaccines, and then we will focus on pharmacies, especially those in rural areas that do not have hospitals or other opportunities to access vaccines outside of the health departments. By enrolling these

pharmacies, we are able to provide vaccine to many of the priority patients. The State will also be deploying vaccination strike teams across the state that will be able to conduct on-site vaccination events for targeted populations that may not have ready access to another vaccine provider. Once hospitals and pharmacies are onboarded, we will begin focusing on large employers, urgent care clinics, and community providers that will be able to reach additional individuals within these priority populations.

C. *Describe how provider enrollment data will be collected and compiled to be reported electronically to CDC twice weekly, using a CDC-provided Comma Separated Values (CSV) or JavaScript (JSON) template via a SAMS-authenticated mechanism.*

Tennessee will generate a CSV file from the Provider Agreement database. The file will be converted into the CDC provided format in SAS and uploaded to SAMS twice weekly.

D. *Describe the process your jurisdiction will use to verify that providers are credentialed with active, valid licenses to possess and administer vaccine.*

Provider licensure information will be pulled from the Provider Agreement database into a CSV file. A preexisting SAS code will compare this file to Tennessee's Licensure Board database for MD, DO, PA, RPh, and NP. The code will match providers on Name, License Type, License Number, Group Number, and contact information. Providers that have a license in good standing will then be compared to Tennessee's Office of the Inspector General's Exclusion List. This check identifies any providers who are barred from participating in federal healthcare programs.

Any provider who is not able to be verified through the automated code will be contacted by VPDIP staff to request the provider's license number and manually check against the Licensure List and Office of the Inspector General's Exclusion List.

E. *Describe how your jurisdiction will provide and track training for enrolled providers and list training topics.*

Tennessee hired a cross-cutting public health educator to work alongside program staff and help develop training for:

- Completing the Provider Agreement and Profile
- Storage and handling
- Vaccine Ordering and Management System (VACCINE ORDERING SYSTEM) training
 - Ordering and receiving vaccine
 - Reconciling vaccine counts
- TennIIS training
 - Entering vaccine
 - Mass Immunization Module

- Providing a strong vaccine recommendation
- EUA Fact Sheets
- Reporting to the Vaccine Adverse Events Reporting System (VAERS)
- Conducting offsite vaccination clinics
- Submitting facility information to CDC's Vaccine Finder
- Vaccine Administration

VPDIP will create a pre-recorded webinar for vaccinating providers that will be required viewing for each facility's primary and back-up pandemic vaccine coordinators. The Program will track provider participation and ensure all pertinent materials are reviewed.

F. *Describe how your jurisdiction will approve planned redistribution of COVID-19 vaccine (e.g., health systems or commercial partners with depots, smaller vaccination providers needing less than the minimum order requirement).*

Tennessee plans to minimize redistribution of COVID-19 vaccine to every extent possible by ensuring appropriate allocation to vaccinating partners; however, some redistribution will be unavoidable. Redistribution will be coordinated centrally to ensure the integrity of the cold chain and, at least initially, vaccine will only be redistributed with the approval and involvement of the VPDIP team. Depending on the circumstances, vaccine may be transported by regional emergency management staff, the local or regional health department, or by members of the National Guard.

G. *Describe how your jurisdiction will ensure there is equitable access to COVID-19 vaccination services throughout all areas within your jurisdiction.*

Tennessee is in the process of onboarding 1,104 initial volunteer vaccine providers, located across the state's 95 counties. Every county has at least one provider among this initial priority group of organizations. In partnership with the TN Pharmacists' Association, local pharmacies will be onboarded as vaccine providers with priority given to those that are in counties where the local health department is currently the only provider of vaccine. Additionally, multiple vaccination strike teams are being deployed across the state to provide additional vaccination opportunities—particularly at locations where vulnerable populations are housed or congregate. In each population group prioritized for vaccination, additional prioritization will be given to geographic areas identified through CDC's Social Vulnerability Index or other index that indicates higher risk of disease burden or severity of outcomes.

H. *Describe how your jurisdiction plans to recruit and enroll pharmacies not served directly by CDC and their role in your COVID-19 Vaccination Program plans.*

VPDIP has a strong relationship with the Tennessee Pharmacy Association (TPA). TPA serves as the central point of contact for pharmacists and provides a conduit for communication to that group of providers. Local pharmacies, especially those in rural regions, will play an important role in providing COVID-19 vaccine in their communities and this group is the second priority for onboarding to the process. VPDIP has already collected information from hundreds of pharmacists so that will be pre-populated into individual database records that parallel the Provider Agreement.

Section 6: COVID-19 Vaccine Administration Capacity

A. Describe how your jurisdiction has or will estimate vaccine administration capacity based on hypothetical planning scenarios provided previously.

In April of 2020, Tennessee began collecting information from organizations that had interest in partnering to administer pandemic vaccines. An initial interest survey was sent to all TennHIS users and licensed physicians and pharmacists. The survey included questions about the capacity to store vaccine and the willingness to vaccinate staff and/or the community. This information paired with GIS mapping of approved vaccine administrators and estimates of priority populations will help VPDIP understand the capacity to provide vaccines. Additionally, the recruitment of rural pharmacists and large corporations that will be able to vaccinate large numbers of individuals from priority populations will provide substantial capacity across the state.

B. Describe how your jurisdiction will use this information to inform provider recruitment plans.

GIS mapping has been used to identify the locations of 1,104 organizations that have expressed initial interest in becoming pandemic vaccine providers. This has allowed the planning team to visualize gaps in access and recruit providers in specific regions. The initial goal is to onboard every hospital, with priority to those with emergency departments and/or intensive care units, followed by local pharmacies that will ensure at least two vaccine administration sites per county. The onboarding of local pharmacies is estimated to add hundreds of vaccine administration sites across the state and provide expanded access to rural communities. Additionally, maps that indicate populations with higher prevalence of conditions or circumstances that increase the risk of significant morbidity and mortality from COVID-19 will be utilized. Particular attention will be paid to those identified areas to ensure vaccine providers are recruited in those geographic areas in sufficient number to vaccinate those at-risk populations. Vaccination strike teams and closed PODs will also be used in these areas to target high-risk populations that may be reluctant or unable to proactively seek out the opportunity to receive the vaccine.

Section 7: COVID-19 Vaccine Allocation, Ordering, Distribution, and Inventory Management

A. Describe your jurisdiction's plans for allocating/assigning allotments of vaccine throughout the jurisdiction using information from Sections 4, 5, and 6. Include allocation methods for populations of focus in early and limited supply scenarios as well as the variables used to determine allocation.

Initially, VPDIP intended to use allocation code adapted from its current influenza vaccine allocation process to determine county, and then facility, allocations. On October 7, 2020, the Program was introduced to the Tiberius application, which appears to be able to make allocation based on several variables easier to determine. This functionality may replace the original plan to use the Program's vaccine allocation code, but the Program has not yet had the opportunity to test the functionality of this application. During Phase 1a allocation (when vaccine supply is restricted), front line health care workers and first responders will be provided the first

opportunity to be vaccinated. As such, initial vaccine allocations will be sent to hospitals with emergency departments and intensive care units, as they see patients with the highest acuity and risk for transmission to their employees. At the same time, county health departments will receive limited doses of vaccine to provide to their first responders. Hospitals and health departments will prioritize health care workers and first responders meeting certain criteria that place them at higher risk of severe morbidity and mortality from COVID-19. Additionally, prioritization will be given to geographic areas identified through CDC's Social Vulnerability Index or other index that indicates higher risk of disease burden or severity of outcomes. During this early Phase of vaccine distribution, local pharmacies will continue to be onboarded in anticipation of the need to vaccinate expanded numbers of individuals in Phases 1b and 1c.

B. *Describe your jurisdiction's plan for assessing the cold chain capability of individual providers and how you will incorporate the results of these assessments into your plans for allocating/assigning allotments of COVID-19 vaccine and approving orders.*

Tennessee's VFC Coordinators and Epidemiologists will assess each storage unit listed by providers on the COVID-19 Provider Agreement. Every storage unit's make and model number will be researched to ensure it meets minimum CDC requirements for vaccine storage, as outlined in the CDC Storage and Handling Toolkit. If a storage unit cannot be located through research, the provider will be asked to send photos of the storage unit. The VFC team may request photos of the thermostat, photos of the unit's interior and exterior, as well as temperature monitoring documentation to ensure the documented storage unit meets CDC requirements and can maintain appropriate vaccine storage temperatures. All providers will be required to submit Digital Data Logger (DDL) Certificates of Calibration for each storage unit, and the VFC team will review each certificate to ensure it meets recommendations outlined in CDC's Storage and Handling Toolkit.

DDLs will be required to have the following features:

- Detachable buffered probe
- Alarm for out of range temperatures
- Low battery indicator
- Current, minimum, and maximum temperature display
- Uncertainty of $\pm 0.5^{\circ}\text{C}$
- Logging interval that can be programmed by the user to measure and record temperatures at least every 30 minutes
- Ability to easily download data for review
- Ability to report temperatures in Celsius

DDL Certificates of Calibration must not be expiring within the next six months and must include the following:

- Model/device name and/or number
- Serial number
- Date of calibration
- Confirmation the instrument passed testing
- Uncertainty of $\pm 0.5^{\circ}\text{C}$

The VFC team will also assess the estimated storage capacity of each vaccine storage unit and will review the availability of the vaccine coordinator for receipt of COVID-19 vaccine shipments as documented on the Provider Agreement. Documentation of the provider's vaccine storage and temperature monitoring equipment and capacity will be maintained in a database. Following review of the provider's vaccine storage and handling capacity, the VFC team will indicate "approved" or "not approved" in the database for each provider's cold chain capacity for refrigerated and frozen vaccine. A provider may be approved to store refrigerated vaccine, frozen vaccine, or both.

COVID-19 vaccine will be allocated to providers based on identified storage capacity and approval status for storage of refrigerated or frozen vaccine. These variables will be analyzed by Program epidemiologists to appropriately allocate the amount and presentation of COVID-19 vaccine for each provider enrolled in the COVID-19 Vaccination Program. Tennessee will leverage its existing seasonal influenza allocation SAS code or allocation functionality through the new Tiberius platform to allocate COVID-19 vaccine to Phase 1 providers, and orders will be approved based on allocated amounts. Once vaccine is available in sufficient quantities to allow providers to place orders instead of receiving vaccine allocations, orders will be approved only after review of a provider's profile information.

C. *Describe your jurisdiction's procedures for ordering COVID-19 vaccine, including entering/updating provider information in VTrckS and any other jurisdictional systems (e.g., IIS) used for provider ordering. Describe how you will incorporate the allocation process described in step A in provider order approval.*

Tennessee's vaccine ordering system team will utilize existing processes to update provider information. Tennessee's epidemiologists have written SAS code to pull information from the database (where all COVID-19 Vaccination Program provider information will be documented) to create a provider profile form export, allowing new provider information to be uploaded to order en masse. The Tennessee Immunization Information System (TennIIS) team will continue to utilize its existing onboarding process for enrolling new providers into the IIS or updating existing providers in the IIS.

For Phase 1, Tennessee will leverage existing seasonal influenza vaccine allocation code or allocation information from the Tiberius platform to output the order file for COVID-19 vaccine. The Program's Central Office staff will then manually place the order in the IIS based on the allocation. The Program will be testing an update to the IIS in October 2020 that includes the ability to utilize a Data Translation Tool (DTT) import file to upload orders into the vaccine ordering system, removing the necessity for the team to manually place these orders should this upgrade be applied to the IIS. Orders will only be entered or uploaded and approved based on amounts allocated through code for Phase 1. Once vaccine is available in sufficient quantities to allow providers to place orders instead of receiving vaccine allocations, orders will be approved only after review of a provider's profile information.

D. Describe how your jurisdiction will coordinate any unplanned repositioning (i.e., transfer) of vaccine.

Tennessee plans to minimize redistribution of COVID-19 vaccine to every extent possible by ensuring appropriate allocation to vaccinating partners; however, some redistribution will be unavoidable. Redistribution will be coordinated centrally to ensure the integrity of the cold chain and, at least initially, vaccine will only be redistributed with the approval and involvement of the State's VPDIP team. Depending on the circumstances, vaccine may be transported by regional emergency management staff, the local or regional health department, or by members of the National Guard.

Tennessee will follow existing VFC Program protocols to coordinate the safe transfer of vaccine in situations of unplanned repositioning. Providers are expected to contact Program staff in the event unplanned repositioning is necessary to prevent wastage of vaccine. All providers will receive an educational packet including this expectation and Program contact information upon enrollment into the COVID-19 Vaccination Program. All COVID-19 vaccine transfers will be conducted with the assistance of a Regional Immunization Representative (RIR). RIRs are located in each rural region and metro in Tennessee and are trained in conducting VFC Program activities, including the safe transfer of vaccines. To ensure cold chain is maintained, RIRs will follow established vaccine transport procedures and use either a portable vaccine refrigerator/freezer or a qualified container and pack-out. DDLs will remain with the vaccine at all times before, during, and after the transfer. All transport requirements and recommendations outlined in section 6 of CDC's Storage and Handling Toolkit will be followed. As vaccine is being initially retrieved, a final inventory reconciliation will be conducted and documented in the IIS' vaccine ordering system. Once the vaccine transfer is complete, the reconciled inventory will be transferred to the receiving facility's inventory by the RIR or Central Office VACCINE ORDERING SYSTEM team and accepted by the provider.

E. Describe jurisdictional plans for monitoring COVID-19 vaccine wastage and inventory levels.

For accurate monitoring of vaccine inventory levels, it is crucial that providers routinely reconcile and accept vaccine orders into their inventory within the IIS. Providers enrolled in the COVID-19 Vaccination Program will be required to reconcile their inventory in the vaccine ordering system every 30 days, at a minimum, as well as accept new orders into their inventory upon receipt of the vaccine. Program epidemiologists will leverage existing SAS code used to monitor VFC Provider ordering and inventory management practices to evaluate adherence to COVID-19 vaccine reconciliation and inventory requirements. If an order is not accepted into a provider's inventory within four business days, the provider will receive an auto-generated email asking them to accept their vaccine order. The vaccine ordering system epidemiologist will run a daily report using IIS data to generate a list of providers who have not accepted an order into their inventory within seven business days. This report will be sent to the vaccine ordering system team for immediate follow-up with the provider. The team's epidemiologist will generate a monthly report utilizing IIS data to identify providers that are not reconciling their inventory every 30 days. These reports will be sent to the team for immediate provider follow-up.

The team's epidemiologist will create code to monitor the reconciliation reasons submitted to the IIS by providers to monitor for high levels of wastage and for any inventory discrepancies that require follow up. The team's epidemiologist will also use IIS data and SAS code to generate reports identifying provider locations that have COVID-19 vaccine inventory set to expire within 90 days so vaccine can be repositioned, if needed, to prevent wastage.

Section 8: COVID-19 Vaccine Storage and Handling

A. Describe how your jurisdiction plans to ensure adherence to COVID-19 vaccine storage and handling requirements, including cold and ultracold chain requirements, at all levels:

- **Individual provider locations**

Cold chain maintenance at individual provider locations will require appropriate vaccine storage and temperature monitoring equipment, a trained provider staff, and consistent, accurate inventory management as already discussed. All enrolled providers will be required to report TEs by the next business day to the Program's VFC Team. Providers are also expected to label vaccine that has undergone a TE as "Do Not Use" and cease administration of the vaccine until stability has been determined by the Program. The VFC Team will have two primary TE contacts assigned to handle incoming TEs per program protocols each day, and support will be provided by TN's VFC Coordinators should the primary TE contacts require assistance. In rare instances, some facilities will have the capacity to store vaccines under ultra-cold storage conditions. Facilities storing vaccines under ultra-cold conditions will be required to monitor unit temperatures with equipment that is appropriate for the monitoring of vaccines stored in that environment. Facilities that fail to report temperature excursions within one business day will be at high risk for wasting vaccine and the need to re-vaccinate patients. Facilities failing to report a temperature excursion and facilities with repeated temperature excursions will be closely monitored and required to submit weekly data logger reports to the program. Facilities identified as having these issues will be reviewed on a case-by-case basis and will risk having their vaccines reallocated to other facilities if these issues are not corrected or if it is determined that the facility is negligent in their handling of vaccines.

Given the expectation that initial allocations of vaccine will require ultra-cold storage and shipped in containers that will require up to 150 lbs. of pelleted dry ice per 1,000 doses of vaccine to maintain those conditions for as long as 14 days, the Program is working with the Tennessee Emergency Management Agency and the Unified Command Group to identify the supply chain and delivery of that resource as vaccine is distributed.

- **Satellite, temporary, or off-site settings**

Satellite, temporary, or off-site vaccine administration settings will require additional care to ensure appropriate vaccine storage and handling is maintained. Tennessee will limit the transport of any frozen or ultra-cold vaccine products and encourage providers to have frozen or ultra-cold vaccine shipped directly to the vaccination site or utilize refrigerated vaccine for mass vaccination events. Providers will be required to adhere to all requirements outlined in CDC's Storage and Handling Toolkit Section Six: Vaccine Transport. Upon enrollment into the COVID-19

Vaccination Program, providers will receive an electronic educational packet that details the requirements for satellite, temporary, or off-site settings.

Providers will be encouraged to review CDC's Guidance for Planning Vaccination Clinics Held at Satellite, Temporary, or Off-Site Locations and CDC's Vaccination Guidance during a Pandemic for additional considerations necessary for vaccination during COVID-19. These documents will be made available to all enrolling providers.

- ***Planned redistribution from depots to individual locations and from larger to smaller locations***

Tennessee plans to have the ability to store vaccine requiring ultra-cold storage vaccines at depots, if necessary. Depots will only be utilized in the event that there is need to store quantities of ultra-cold vaccine for the purpose of mass vaccination events and closed PODs. Vaccine temperatures will be continuously monitored according to established protocols, and vaccine will only be distributed from these depots to TDH vaccination strike teams or regional health departments conducting mass immunization events.

Tennessee plans to minimize redistribution of COVID-19 vaccine to every extent possible by ensuring appropriate allocation to vaccinating partners; however, some redistribution will be unavoidable. Redistribution between individual facilities will be coordinated centrally to ensure the integrity of the cold chain and, at least initially, vaccine will only be redistributed with the approval and involvement of the VPDIP team. Depending on the circumstances, vaccine may be transported by regional emergency management staff, the local or regional health department, or by members of the National Guard.

- ***Unplanned repositioning among provider locations***

Tennessee will follow existing VFC Program protocols to coordinate the safe transfer of vaccine in situations of unplanned repositioning. Providers are expected to contact Program staff in the event unplanned repositioning is necessary to prevent wastage of vaccine. All providers will receive an educational packet including this expectation and Program contact information upon enrollment into the COVID-19 Vaccination Program. All COVID-19 vaccine transfers will be conducted with the assistance of a Regional Immunization Representative (RIR). RIRs are located in each rural region and metro in Tennessee and are trained in conducting VFC Program activities, including the safe transfer of vaccines. To ensure cold chain is maintained, RIRs will follow established vaccine transport procedures and use either a portable vaccine refrigerator/freezer or a qualified container and pack-out. DDLs will remain with the vaccine at all times before, during, and after the transfer. DDL reports will be evaluated for TEs prior to vaccine transport, as well as after transport to the receiving facility is completed. All transport requirements and recommendations outlined in section 6 of CDC's Storage and Handling Toolkit will be followed.

B. Describe how your jurisdiction will assess provider/redistribution depot COVID-19 vaccine storage and temperature monitoring capabilities

Tennessee will not allow providers to redistribute COVID-19 vaccine through depots and has no intention of distributing vaccines from the TDH depots to providers outside of TDH's oversight.

Section 9: COVID-19 Vaccine Administration Documentation and Reporting

A. Describe the system your jurisdiction will use to collect COVID-19 vaccine doses administered data from providers.

Tennessee will use the Tennessee Immunization Information System (TennIIS) to collect COVID-19 vaccine doses administered by providers. TennIIS is a Software as a Service (SAAS) platform that is maintained by STChealth. The VPDIP program manages TennIIS and supports its users. As of October 2020, TennIIS holds +8.2 million patients and +78 million vaccinations. TennIIS has +13,500 users across +5,700 facilities. Of these 5,700 facilities, 44% report data to TennIIS via direct data entry using the TennIIS iWeb web portal, 35% report data electronically sending HL7 messages via a batch process, and 21% report data via real-time HL7 messaging.

Below is a visual overview of how TennIIS functionality will be used to collect vaccine doses administered:

- During the Limited Vaccine Availability Phase, TennIIS' Mass Immunization Module will be leveraged by those providers who don't have an electronic interface in place between their Electronic Health Record system (EHR) and TennIIS.
- During the phases where vaccine will be more widely available, TennIIS' iWeb Module will be used by those providers who don't have an electronic interface in place between their Electronic Health Record system (EHR) and TennIIS.

B. Describe how your jurisdiction will submit COVID-19 vaccine administration data via the Immunization (IZ) Gateway.

COVID-19 vaccine information will be collected through TennIIS and sent to CDC via the IZ Gateway.

The TennIIS team is working with TDH's IT team, STChealth and AIRA to implement the IZ Gateway Connect and Share components.

C. Describe how your jurisdiction will ensure each COVID-19 vaccination provider is ready and able (e.g., staff is trained, internet connection and equipment are adequate) to report the required COVID-19 vaccine administration data elements to the IIS or other external system every 24 hours.

Ensuring that each COVID-19 vaccination provider is ready and able to report the required COVID-19 vaccine administration data elements to TennIIS is a part of the COVID-19 provider onboarding process. As COVID-19 providers are going through the onboarding process, the VPDIP onboarding team makes sure that every provider meets three overall requirements:

- a. The COVID-19 Provider Agreement and Profile has been completed and signed
- b. The facility where the vaccine will be stored meets the Storage and Handling Requirements
- c. The facility and its staff are registered as TennIIS users

If the provider is linked to a facility or organization that is already registered in TennIIS, the TennIIS team checks and makes sure that the facility is active, that active users are associated with the facility (if direct data entry provider) and that electronic messages are being exchanged (if an electronic data exchange provider). Communications from the TennIIS team to the existing providers inform these providers of the requirement to report COVID-19 vaccine data within 24 hours of the administration of the vaccine.

If the provider is linked to a facility or organization that is not already registered in TennIIS, the TennIIS Registration team will register the organization or facility and set-up the users that are linked to these entities. Next, the TennIIS Registration team sends out a “welcome” email that includes the TennIIS Quick Reference Guide for Medical Office Users. If the provider is interested in building an electronic connection between the provider’s EHR system and TennIIS, the TennIIS Electronic Data Exchange team will work with the provider and the EHR vendor to implement an electronic connection.

The TennIIS epidemiologists will create reports that evaluate timeliness and completeness of reporting of COVID-19 vaccine administration at the organization and facility level. This report will include flags for follow-up that will be based on the percentage of errors and delays in reporting. This report will be viewed on a daily basis by the TennIIS Registration (direct data entry COVID-19 providers) and Electronic Data Exchange (electronic data exchange COVID-19 providers) teams. These teams will reach out to the COVID-19 providers who are not reporting every 24 hours and help with troubleshooting barriers to successful reporting.

D. Describe the steps your jurisdiction will take to ensure real-time documentation and reporting of COVID-19 vaccine administration data from satellite, temporary, or off-site clinic settings.

The satellite, temporary and off-site clinics will use TennIIS’ Mass Immunization Module to document COVID-19 vaccine administration at the time of the mass vaccination event. All public health clinics have been trained on TennIIS’ Mass Immunization Module and will be using this module during this fall’s flu mass vaccination events and during the Fight Flu TN event. This will prepare public health users for documenting COVID-19 vaccine administration later this year. Any non-public health site that will be hosting a mass vaccination event can access the Mass Immunization Module Quick Reference Guide and reach out to TennIIS.Training@tn.gov when in need of additional assistance.

E. Describe how your jurisdiction will monitor provider-level data to ensure each dose of COVID-19 vaccine administered is fully documented and reported every 24 hours as well as steps to be taken when providers do not comply with documentation and reporting requirements.

The TennIIS epidemiologists will create reports that evaluate timeliness and completeness of the reporting of COVID-19 vaccine administration at the organization and facility level. This report will include flags for follow-up that will be based on the percentage of errors and delays in

reporting. Vaccine administration data that are submitted more than 24 hours after the vaccine administration date will be flagged as will providers who have not reported data within the past 48 hours.

The VPDIP team is in the process of defining flag thresholds, e.g. flag when X % of administered COVID vaccinations were reported without / with invalid Y field. (ex. Lot number or NDC code)

The TennIIS Registration (if direct data entry COVID-19 providers) and Electronic Data Exchange (if electronic data exchange COVID-19 providers) teams will review this report on a daily basis. Below is the process that the TennIIS Registration and Electronic Data Exchange teams will follow when troubleshooting vaccine reporting issues with COVID-19 providers:

Ongoing: monitor organizations that are submitting immunizations and identify gaps within their submissions. Gaps are identified in the above-mentioned report. This report will be stored on the shared network.

Step 1: Navigate to the most recent spreadsheet. The most recent spreadsheet will be uploaded daily, Monday through Friday. Dates will be indicated in the filename.

Step 2: Filter for highest priority groups (based on the flags that need to be defined).

Step 3: Check practices with >24 hour delay in reporting and/or last submission date over 48 hours ago, use email to reach out to that provider and (if electronic trading partner) their EHR vendor.

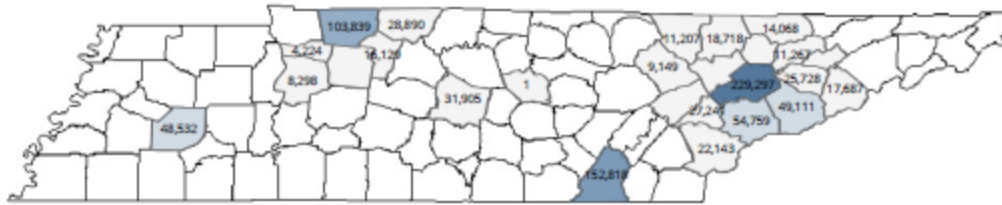
F. Describe how your jurisdiction will generate and use COVID-19 vaccination coverage reports.

Every day, Monday through Friday, a report and dashboard visualizing vaccination data received from COVID providers will be generated from TennIIS. This dashboard will report both patient demographics and organization/facility information, incorporating census data for coverage and geographic estimates.

Below are proposed COVID-19 Vaccine coverage reports:

Tennessee COVID-19 Vaccine Reporting

Vaccine Reported by Patient County

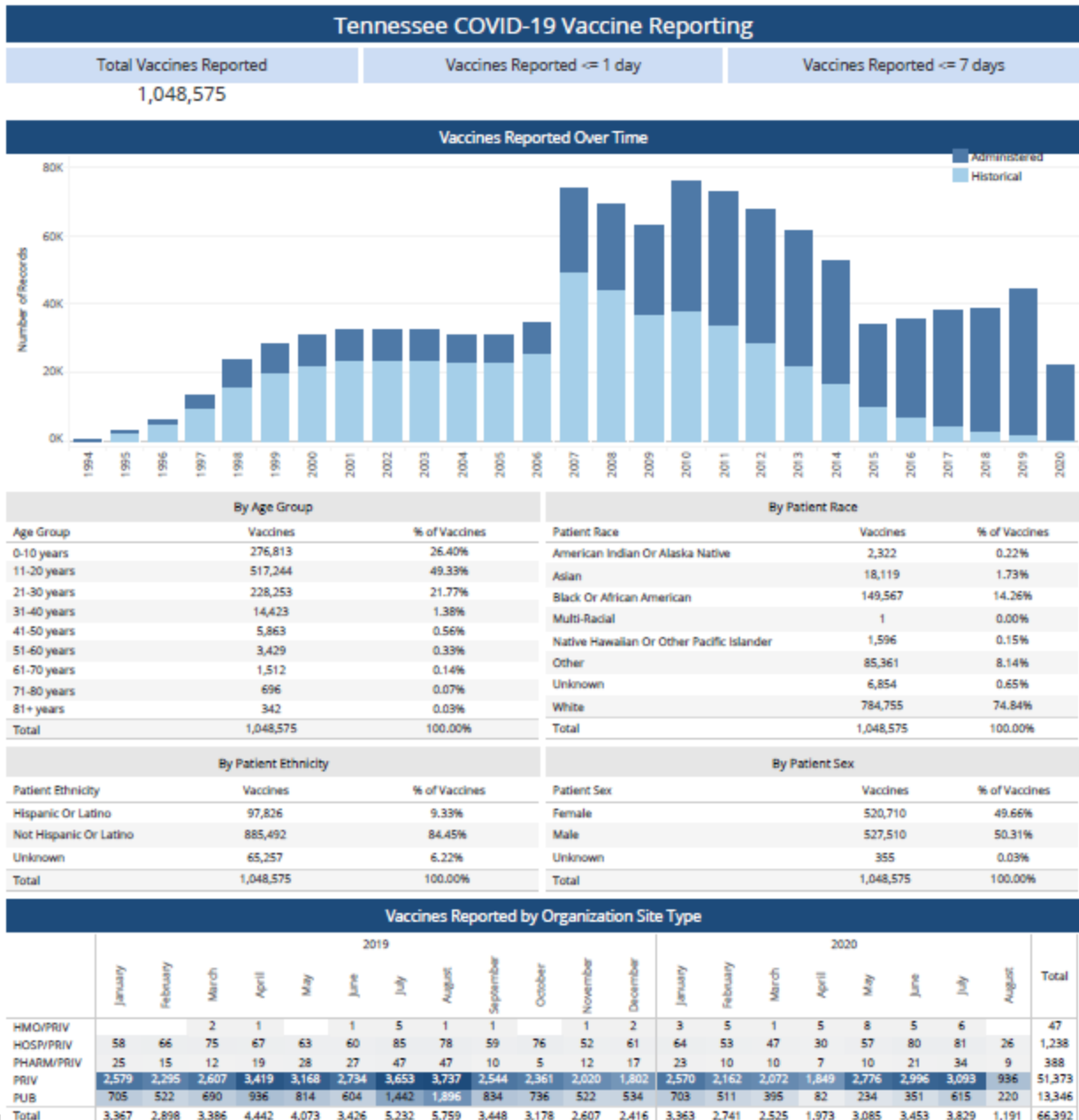


Vaccination Rates by Patient County

Patient County	County Vaccine Count	Population 2019	County Vaccination Rate per 100,000
ANDERSON	31,062	76,978	40,352
BLOUNT	54,790	133,084	41,169
CAMPBELL	18,731	39,842	47,013
CHEATHAM	16,130	40,668	39,663
CLAIBORNE	14,071	31,959	44,028
COCKE	17,687	35,998	49,133
DICKSON	21,321	53,943	39,525
GRANGER	11,267	23,315	48,325
HAMBLEN	32,303	64,932	49,749
HAMILTON	152,997	367,804	41,597
HOUSTON	4,246	8,221	51,648
HUMPHREYS	8,305	18,574	44,713
JEFFERSON	26,066	54,488	47,838
KNOX	229,404	470,307	48,778
LOUDON	27,250	54,069	50,399
MADISON	49,383	97,981	50,401
MONROE	22,296	46,554	47,893
MONTGOMERY	104,023	208,997	49,772
MORGAN	9,229	21,393	43,140
ROANE	18,566	53,387	34,776
ROBERTSON	35,578	71,813	49,543
RUTHERFORD	140,212	332,278	42,197
SCOTT	13,334	22,062	60,439
SEVIER	49,127	98,254	50,000
UNION	7,306	19,966	36,592

Vaccines Reported by CVX Code

CVX Code	CVX Description	2019												2020								Total
		January	February	March	April	May	June	July	August	September	October	November	December	January	February	March	April	May	June	July	August	
21	VARICELLA	3,076	2,583	2,937	3,767	3,259	2,638	3,843	4,207	2,624	2,413	1,968	1,886	2,581	2,041	1,856	1,455	2,122	2,235	2,434	717	50,642
94	MMRV	291	315	449	675	814	788	1,389	1,552	824	765	639	530	782	700	669	518	963	1,218	1,395	474	15,750
Total		3,367	2,898	3,386	4,442	4,073	3,426	5,232	5,759	3,448	3,178	2,607	2,416	3,363	2,741	2,525	1,973	3,085	3,453	3,829	1,191	66,392



Below are proposed uses for COVID-19 vaccination coverage reports:

- Ensure COVID-19 vaccine providers are administering allocated vaccine and follow-up with providers via email if they have not submitted vaccine administration data into TennIIS within a certain number of days
- Verify COVID-19 vaccinating providers are submitting data into TennIIS within 24-hours of vaccine administration
- Track vaccine wastage via vaccine administration; data may be triangulated with vaccine ordering

- Ensure vaccines are coded appropriately into TennIIS as administered vs. historical doses
- Encourage vaccinating providers to submit patient phone and address data
- Determine gaps in vaccine administration across geographic or demographic populations to inform targeted outreach efforts

Section 10: COVID-19 Vaccination Second-Dose Reminders

A. *Describe all methods your jurisdiction will use to remind COVID-19 vaccine recipients of the need for a second dose, including planned redundancy of reminder methods.*

Method 1: TDH/VPDIP will encourage all COVID-19 vaccinating providers to give out a paper copy of proof of vaccination to every individual that receives their first dose of COVID-19 vaccine. This paper copy will also indicate the date when the individual is due for their second dose of COVID-19 vaccine, if applicable. The paper copy may be a COVID-19 vaccination record card provided as part of vaccine ancillary kits by CDC, a vaccination record card provided by the Tennessee Department of Health (TDH), or a printed copy of proof of vaccination from the provider's EHR and/or the Tennessee Immunization Information System (TennIIS). This record may include the following information: patient first and last name, patient date of birth, date of first COVID-19 vaccine dose administration and date for subsequent dose (if indicated), facility name where patient received first COVID-19 vaccine dose, vaccine manufacturer, and vaccine lot number. TDH/VPDIP will encourage providers that have the capability to schedule second dose appointments when the individual receives their first dose.

Method 2: TDH/VPDIP will leverage TennIIS to send reminder/recall (R/R) text messages to individuals who require a second dose of COVID-19 vaccine. During Phase 1 of limited vaccine availability, VPDIP will pull data from TennIIS to generate a list of individuals who received their first dose and are coming due for their second dose. Reminder text messages will be sent to individuals reminding them that they are due for their second dose of COVID-19 vaccine in five days. Recall text messages will be sent to individuals who are past-due, encouraging them to get their second dose as soon as possible. Reminder/recall text messages will be sent at least once per week and as needed. To comply with HIPAA regulations, text messages will not include private information but will send the recipient to the TDH/COVID-19 vaccine website that will display a general message about the importance of receiving the second dose of COVID-19 vaccine. This message will appear in multiple languages and include information about how to find COVID-19 vaccinating providers in TN. During Phase 2 of general vaccine availability, TDH/VPDIP will continue to send R/R text messages, but R/R may also be conducted by vaccinating facilities using the TennIIS Reminder/Recall functionality.

Method 3: TDH/VPDIP will encourage all COVID-19 vaccinating providers to send out reminder/recall notice(s) to every individual to whom they administered a COVID-19 vaccine that requires a second dose. TDH/VPDIP will also provide training materials on how providers may use the Reminder/Recall functionality in TennIIS to generate a list of patients who are due to receive the second dose within the next 5-7 days, and/or those who are overdue for their second dose.

Starting November 1, 2020, VPDIP will require phone numbers to be entered when manually creating or updating patient records in TennIIS. The importance of entering a patient's phone number into TennIIS will be communicated across all COVID-19 vaccinating providers. This will assist with the response rate of R/R activities conducted via text messages and/or phone calls.

Section 11: COVID-19 Requirements for IISs or Other External Systems

- A. *Describe your jurisdiction's solution for documenting vaccine administration in temporary or high-volume vaccination settings (e.g., CDC mobile app, IIS or module that interfaces with the IIS, or other jurisdiction-based solution). Include planned contingencies for network outages or other access issues.***

The temporary and high-volume vaccination clinics will use TennIIS' Mass Immunization Module to document COVID-19 vaccine administration at the time of the mass vaccination event. The TennIIS Mass Immunization Module is an integral part of, and is built into, the IIS, eliminating the need to build an interface.

The Mass Immunization Module allows for faster data entry during mass vaccination events as Lot Number Defaults are added prior to conducting these events. Setting the default lot number(s) results in the lot number being automatically populated in the patient's TennIIS record. When the administered vaccine and lot number are added to the patient record, the vaccine dose is subtracted from the TennIIS inventory, maintaining vaccine dose accountability and accurate inventory management.

All Public Health clinic users have been trained on TennIIS' Mass Immunization Module and will be using this module during this fall's Fight Flu TN mass vaccination events. Any non-public health site that will be hosting a mass vaccination event can access the Mass Immunization Module Quick Reference Guide and reach out to TennIIS.Training@tn.gov when in need of additional assistance.

As TennIIS is a web-based system, outages are uncommon. Federal funding is being used to purchase remote internet hot spots that will allow for data entry at sites without internet access. In the event that TennIIS is unavailable, vaccine administration information will be recorded on paper logs or in Excel spreadsheets that will be transcribed into TennIIS when access returns.

- B. *Planned contingencies for network outages or other access issues.***

The planned contingencies for network outages or other access issues is ensuring that blank vaccine administration sheets are available in hard copy (paper copies) and in soft copy on the mass vaccination user desktops/laptops (i.e., Excel spreadsheets).

- C. *List the variables your jurisdiction's IIS or other system will be able to capture for persons who will receive COVID-19 vaccine, including but not limited to age, race/ethnicity, chronic medical conditions, occupation, membership in other critical population groups.***

The following is the list of the required and optional data elements that CDC is proposing IISs report, and the ability of these data elements to be captured in TennIIS iWeb (manual data entry via TennIIS web portal), TennIIS Mass Immunization Module (manual data entry via TennIIS Mass Immunization web portal) and TennIIS PHC Hub (electronic exchange):

Data elements required for IIS to report	Can be captured in TennIIS iWeb portal?	Can be captured in TennIIS Mass IMM module?	Can be captured in TennIIS PHC Hub (Electronic Data Exchange)?
Administered at location: facility name/ID	Yes	Yes	Yes (RXA 11)
Administered at location: type	Yes	Yes	No
Administration address (including county)	Yes	Yes	Yes (RXA 11.9-11.15)
Administration date	Yes	Yes	Yes (RXA 3)
CVX (Product)	Yes	Yes	Yes- or NDC (RXA 5)
Dose number	Yes	Yes	No
IIS Recipient I	Yes	Yes	Yes (PID 3 as SR)
IIS vaccination event ID	No	No	No
Lot Number: Unit of Use and/or Unit of Sale	Yes	Yes	Yes (RXA 15)
MXV (Manufacturer)	Yes	Yes	Yes (RXA 17)
Recipient address	Yes	Yes	Yes (PID 11)
Recipient date of birth	Yes	Yes	Yes (PID 7)
Recipient name	Yes	Yes	Yes (PID 5)
Recipient sex	Yes	Yes	Yes (PID 8)
Sending organization	Yes	Yes	Yes (MSH 4)
Vaccine administering provider suffix	Yes	Yes	No
Vaccine administering site (on the body)	Yes	Yes	Yes (RXR 2)
Vaccine expiration date	No	No	Yes(RXA 16)
Data elements required for IIS to report	Can be captured in TennIIS iWeb portal?	Can be captured in TennIIS Mass IMM module?	Can be captured in TennIIS PHC Hub (Electronic Data Exchange)?
Vaccine route of administration	Yes	Yes	Yes(RXR 1)
Vaccination series complete	No	No	No
Comorbidity status (Y/N)	No	No	No
Mass Vaccination	No	No	No
Recipient ethnicity	Yes	Yes	Yes(PID 22)

Recipient race	Yes	Yes	Yes (PID 10)
Recipient missed vaccination appointment (Y/N)	No	No	No
Vaccination Refusal (Y/N)	No	No	Yes (RXA 3, RXA 18)
Other Data elements	Captured and Required in TennIIS iWeb portal?	Captured and Required in TennIIS Mass IMM module?	Captured and Required via Electronic Data Exchange?
Chronic Medical Conditions	No	* No	No
Occupation	No	* No	No
Membership in Other Critical Population Groups	No	* No	No

(*) Populations may be able to be defined as “tiers” in the mass immunization module, allowing for tracking of these groups.

D. Describe your jurisdiction’s current capacity for data exchange, storage, and reporting as well as any planned improvements (including timelines) to accommodate the COVID-19 Vaccination Program. Current numbers (patients, vaccinations, providers). Efforts to improve capacity:

TennIIS is a Software as a Service (SAAS) platform that is maintained by STChealth. STChealth maintains TennIIS and provides the patches and fixes to the STChealth proprietary code. The VPDIP program manages TennIIS and supports its users. As of October 2020, TennIIS holds +8.2 million patients and +78 million vaccinations. TennIIS has +13,500 users across +5,700 facilities. Of these 5,700 facilities, 44% report data to TennIIS via direct data entry using the TennIIS iWeb web portal, 35% report data electronically sending messages via a batch process, and 21% report data via real-time messaging.

The TennIIS and VPDIP epidemiologists use SAS and Tableau to analyze and visualize TennIIS data.

VPDIP has been working with the STC and TDH IT teams to update TennIIS servers in the cloud.

On Sept. 1, 2020, TDH signed an emergency contract with STC. Through this contract, STC is developing and implementing functionality that will facilitate rapid and streamlined (pandemic) registration at the organization, facility and user levels. This includes streamlining provider site types for TennIIS organizations and facilities, adding a flag to indicate which providers are pandemic vaccine providers, adding a Pandemic PIN, and adding a self-service workflow for all aspects of registration that will allow TennIIS staff to quickly make changes to registration forms/requirements and independently respond to current needs without involving the TennIIS vendor. An expedited user level request form will reduce the burden on TennIIS staff. This functionality will be delivered in phases starting with the October 2020 software release and ending with the February 2021 release.

E. Describe plans to rapidly enroll and onboard to the IIS those vaccination provider facilities and settings expected to serve healthcare personnel (e.g., paid and unpaid personnel working in healthcare settings, including vaccinators, pharmacy staff, and ancillary staff) and other essential workers.

Tennessee's first priority is to onboard hospitals and pharmacies that can administer vaccines to healthcare personnel. The vast majority of the Tennessee hospitals and all major pharmacy chains report immunizations to TennIIS via an electronic interface between their EHR systems and TennIIS. If the connection between the EHR and TennIIS is currently not a real-time, bi-directional interface, we have been working with these entities and their EHR vendors to try to upgrade their interface.

All public health users have been trained on TennIIS iWeb and TennIIS Mass Immunization Module. Tennessee's public health patient management system has a real-time bi-directional interface with TennIIS.

Those providers that do not already have an electronic interface between their EHR and TennIIS, or aren't already registered in TennIIS, will be registered by the TennIIS registration team and will receive TennIIS iWeb and TennIIS Mass Immunization module training.

F. Describe your jurisdiction's current status and plans to onboard to the IZ Gateway Connect and Share components.

The following agreements are in place:

1. Data use agreement between the Tennessee Department of Health (TDH) and the Association of Public Health Laboratories (APHL) to participate in the IZ Gateway.
2. Business Associates Agreement between TDH and APHL.
3. Memorandum of Understanding between TDH and AIRA to share data with other jurisdictions via the IZ Gateway Share component.

The Data Use Agreement between TDH and CDC for sending COVID-19 data to the CDC Data Lake has not been made available by CDC. This agreement will have to be reviewed and approved by TDH Legal, Security and IT before data may be shared with CDC.

G. Describe planned backup solutions for offline use if internet connectivity is lost or not possible.

The planned back-up solution for offline use of the IZ Gateway Connect component is compiling a CSV file of the data elements and sending the data to the CDC via a transfer SFTP site.

In the event of a loss of connectivity with the IZ Gateway Share component, STC will queue outgoing messages from Tennessee to be backloaded to IZ Gateway Share upon return of TennIIS connectivity.

H. *Describe how your jurisdiction will monitor data quality and the steps to be taken to ensure data are available, complete, timely, valid, accurate, consistent, and unique*

A team of TennHIS epidemiologists is building code using SAS to extract data from the Provider Enrollment database and the TennHIS database and compile bi-weekly reports for submission to CDC. Provider Enrollment data is deduplicated as data are collected to the database. All members of this team will have access to upload Tennessee reports into Secure Access Management Services (SAMS); this redundancy will ensure reports are submitted in a consistent and timely manner.

Section 12: COVID-19 Vaccination Program Communication

A. *Describe your jurisdiction's COVID-19 vaccination communication plan, including key audiences, communication channels, and partner activation for each of the three phases of the COVID-19 Vaccination Program.*

- *Healthcare Associations-* TDH has engaged state healthcare associations and professional societies in the creation of Tennessee's plan and will have ongoing scheduled meetings within and external to the larger Stakeholder Group. These associations are already assisting with the recruiting of pandemic providers and the relaying of messages to their constituents.
- *Pandemic Vaccine Planning Stakeholder Meeting-* TDH convenes a bi-weekly Planning Stakeholder Meeting that currently includes representatives of 28 partnering agencies and offices. This group was instrumental in the vetting of the initial plans for the phased roll-out of vaccine to priority populations and will continue to provide expertise and feedback to the Program for as long as necessary.
- *TNHAN direct to providers-* TNHAN announcements will be used to communicate critical information surrounding vaccine allocation, distribution, administration, and reporting, as needed, throughout the implementation of this plan.
- *Additional media campaigns-* The creation, timing, and utilization of COVID-19-related media campaigns is at the discretion of the Governor's office.
- *TDH Pandemic Vaccine website-* The Program has drafted two pandemic vaccine-related web pages—one where the public may find information around developments in pandemic vaccine and its distribution, and the second to provide onboarding information to possible pandemic vaccine providers. Each of these sites will be accessed through TDH's existing COVID-19 resources website.
- *CDC Vaccine finder website –* The CDC Vaccine Finder website link will be placed on the vaccine information webpage and pandemic providers will be asked to participate.

B. *Describe your jurisdiction's expedited procedures for risk/crisis/emergency communication, including timely message development as well as delivery methods as new information becomes available.*

TDH is well-prepared to communicate rapidly through the channels described above.

Section 13: Regulatory Considerations for COVID-19 Vaccination

- A. Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers are aware of, know where to locate, and understand the information in any Emergency Use Authorization (EUA) fact sheets for providers and vaccine recipients or vaccine information statements (VISs), as applicable.**

Emergency Use Authorization fact sheets will be given to the providers in their training materials and discussed during training webinars and communications. The federal requirement to distribute these materials, along with any applicable VISs, will be communicated to all vaccine providers.

- B. Describe how your jurisdiction will instruct enrolled COVID-19 vaccination providers to provide Emergency Use Authorization (EUA) fact sheets or vaccine information statements (VISs), as applicable, to each vaccine recipient prior to vaccine administration.**

Providers will receive an electronic educational packet upon enrollment into the COVID-19 Vaccination Program. Guidance documents will include the product-specific EUA fact sheets for COVID-19 vaccination providers and the EUA fact sheets for vaccine recipients or VISs, once they are made available by CDC. Providers will be instructed to read both types of EUA fact sheets and VISs and reach out to the Program with any questions prior to beginning administration of COVID-19 vaccine. Providers will also be informed through the educational packet of the federal requirement to provide the recipient fact sheet or VIS to each patient prior to vaccine administration. The fact sheets and VISs will also be linked on TDH's COVID-19 website, located where other relevant information for providers is contained. Updates to EUAs or VISs will be distributed via a Listserv or a COVID-19 provider distribution email group and posted to the COVID-19 website. Information about EUA fact sheets and VISs will also be included in tabletop exercises conducted across the state.

Section 14: COVID-19 Vaccine Safety Monitoring

- A. Describe how your jurisdiction will ensure enrolled COVID-19 vaccination providers understand the requirement and process for reporting adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).**

Providers will receive an electronic educational packet upon enrollment into the COVID-19 Vaccination Program. Guidance documents will include information on required reporting of vaccine adverse events to the Vaccine Adverse Event Reporting System (VAERS). Use of the online reporting tool will be demonstrated during training webinars and tabletop exercises, and the link to the VAERS site will be posted on TDH's COVID-19 website, located where other relevant information for providers is contained. Reports made to VAERS will be reviewed by the Medical Director of the Vaccine-Preventable Diseases and Immunization Program.

Section 15: COVID-19 Vaccination Program Monitoring

- Describe your jurisdiction's methods and procedures for monitoring progress in COVID-19 Vaccination Program implementation.**

- **Provider enrollment**

Provider enrollment is monitored through a database that tracks progress through the three stages of onboarding: TennIIS enrollment, storage and handling capabilities, and submission of the completed CDC Provider Agreement and Profile. The location of providers is also mapped via GIS so that geographic coverage of providers may be monitored and providers recruited in areas where there are gaps.

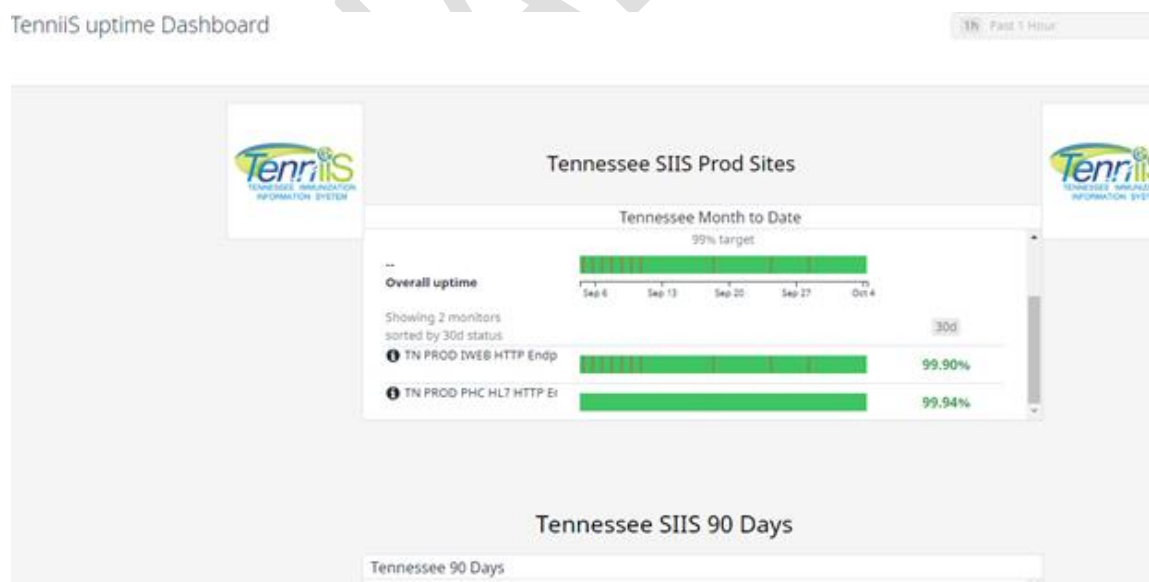
- **Access to COVID-19 vaccination services by population in all phases of implementation**

The Program's understanding is that there is functionality in the Tiberius platform that is capable of assisting with the monitoring of vaccines administered to specific populations. Tennessee is also able to capture data through the mass immunizations module by setting "tiers" that indicate population groups. GIS mapping of provider locations will also assist in ensuring that locations with high-risk populations have sufficient access to vaccinating providers, and vaccination strike teams and the recording of other closed POD events will also provide details to specific populations that are provided vaccine.

- **IIS or other designated system performance**

STC provides 24/7 monitoring of the TennIIS production instance which includes memory, disk, processing and network loads. STC is automatically notified when instance issues arise and will attempt to remediate the issue without impacting TennIIS users. If the steps required to remediate the issue do result in a client-facing impact, STC's Operations team coordinates with the TennIIS Director or Deputy Director via the support team to outline the issue, steps to remediate, and gain approval to execute the remediation plan.

The TennIIS team also has access to the following TennIIS uptime dashboard:



- **Data reporting to CDC**

VPDIP will report bi-weekly to CDC via CSV file upload of CDC Provider Agreements and Profiles.

- ***Provider-level data reporting***

The TennIIS epidemiologists will create a report that evaluates timeliness and completeness of reporting of COVID-19 vaccine administration at the organization and facility levels. This report will include flags for follow-up that will be based on the percentage of errors and delays in reporting. There will be a flag for when a vaccine is submitted >24 hours after the administration date and a flag for when a provider has not reported vaccine administration in more than 48 hours.

The VPDIP team is in the process of defining flag thresholds, e.g. flag when X % of administered COVID vaccinations were reported without / with invalid Y field. (ex. Lot number or NDC code)

The TennIIS Registration (if direct data entry COVID-19 providers) and Electronic Data Exchange (if electronic data exchange COVID-19 providers) teams will review this report on a daily basis.

- ***Vaccine ordering and distribution***

Enrollment into the COVID-19 Vaccination Program will be monitored using data from VPDIP's provider tracking database and data visualization software. VPDIP epidemiologists will utilize data exports from the database and SAS code to generate a weekly update to a dashboard. This will allow metrics such as the number of providers with VPDIP-approved storage and handling, the number of COVID-19 vaccination providers onboarded into the IIS, and the number of providers with a complete COVID-19 Provider Agreement to be visualized. This data will be used to inform how many providers have been onboarded into the COVID-19 Vaccination Program and are therefore eligible to begin receiving vaccine allocations or be approved for ordering.

Vaccine distribution will be monitored by leveraging TN's existing influenza allocation summary SAS code or data available through the Tiberius platform. Allocation code will be updated to include base metrics for the amount of vaccine to be allocated, including the number of patients, number of staff, capacity, county, etc., as identified in sections 3 and 4 of this document. Each time TN receives a vaccine allocation from CDC, the amount distributed to a provider will be determined by these metrics. The code will output a summary that is updated after each allocation to track the number of vaccines distributed to each location by NDC code/presentation and will be marked complete when the base metrics are met.

Vaccine ordering will be monitored using SAS-generated reports created by VPDIP epidemiologists. VPDIP will leverage existing SAS code used to monitor VFC Provider ordering and inventory management practices and evaluate adherence to COVID-19 vaccine reconciliation and inventory requirements. If an order is not accepted into a provider's inventory within four business days, the provider will receive an auto-generated email asking them to accept their vaccine order. The epidemiologist will run a daily report using

IIS data to generate a list of providers who have not accepted an order into their inventory within seven business days. This report will be sent to the team for immediate follow-up with the provider. The epidemiologist will generate a monthly report utilizing IIS data to identify providers that are not reconciling their inventory every 30 days. These reports will be sent to the team for immediate provider follow-up.

- ***1- and 2-dose COVID-19 vaccination coverage***

Every day, Monday through Friday, a report and dashboard visualizing vaccination data received from COVID providers will be generated from TennIIS. This dashboard will report both 1- and 2-dose COVID-19 vaccination administration data compared to county and/or region census data for coverage and geographic estimates.

- ***Describe your jurisdiction's methods and procedures for monitoring resources, including:***

- ***Budget*** – The senior leadership team meets with the program Fiscal Administrator each month to review the budget and verify that funds are being spent appropriately and on track to be fully expended by the end of the budget period.
- ***Staffing*** – The senior leadership team meets weekly to discuss staffing needs, discuss capacity, anticipate demands, and redirect resources, as needed.
- ***Supplies*** – The VPDIP Operations and Administration Director works with the Emergency Preparedness Program to ensure that supplies are ordered and delivered on-time and that future needs are anticipated.

- ***Describe your jurisdiction's methods and procedures for monitoring communication, including:***

- ***Message delivery***

The Program will ensure that provider training documents are received and reviewed by requiring acknowledgement of receipt and attestation of review. Pandemic-related communications that are critical to the health care workforce will be shared via the Tennessee Health Alert Network. Public communications may be monitored through social media site metrics and views.

- ***Reception of communication messages and materials among target audiences throughout jurisdiction***

The Pandemic Vaccine Planning Stakeholder Group will be a conduit through which feedback from constituents may be shared with the State, including the reception of messages by target audiences. Additionally, the Group may be used to vet messaging prior to its dissemination to ensure messages are crafted in a way that resonates with those audiences.

- ***Describe your jurisdiction's methods and procedures for monitoring local-level situational awareness (i.e., strategies, activities, progress, etc.).***

Eighty-nine of Tennessee's 95 counties are under the jurisdiction of TDH and supervised centrally. This results our ability to communicate quickly and effectively with these local jurisdictions. Additionally, TDH has close relationships with the health departments that are

located in Tennessee's six metropolitan jurisdictions and communications channels are well-established. The Pandemic Vaccine Planning Stakeholder Group involves representatives of more than 28 different offices and organizations, both within and outside of state and local government. Each of these representatives is able to communicate messaging back to their constituents, as well as relay information to TDH, to ensure there is local-level situational awareness of TDH activities and statewide progress, as well as awareness of local activities at the state level. Additionally, the Governor's office and the Unified Command Group are regularly updated as to progress and are able to send public messaging, when appropriate.

Public-facing information will be posted to the COVID-19 website (or another designated site) as described below.

- ***Describe the COVID-19 Vaccination Program metrics (e.g., vaccination provider enrollment, doses distributed, doses administered, vaccination coverage), if any, that will be posted on your jurisdiction's public-facing website, including the exact web location of placement.***

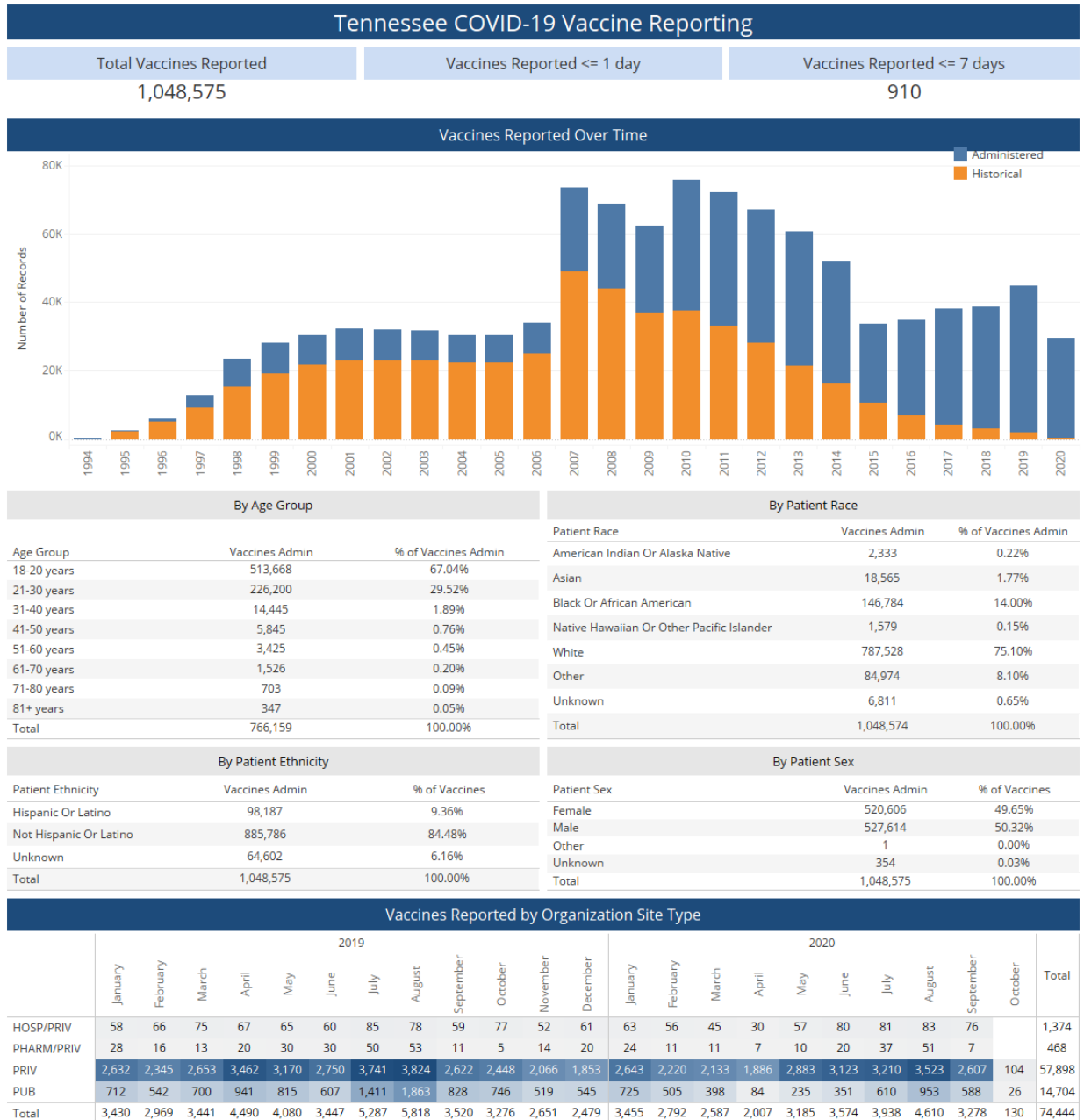
Publicly-reported vaccination program metrics may mimic the current format used to report COVID-19 metrics on the THD public website (<https://www.tn.gov/health/cedep/ncov/data.html>). Vaccination program metrics will be pulled from TennIIS and visualized using SAS and Tableau software. Vaccine metrics will be limited by TennIIS' data availability and data quality. The exact location for publicly available vaccination program metrics is yet to be determined.

Below are the initial COVID-19 Vaccination Program metrics, which may be expanded upon as needed, throughout vaccine distribution roll-out.

1. Number of facilities reporting COVID-19 vaccine administration to TennIIS
 - a. Broken down by 1) public/private provider; 2) Direct Data Entry (DDE) vs. HL7 provider; and 3) by organization site type
2. Number of COVID vaccine doses administered (total)
 - a. # vaccines administered by organization site type (e.g., PUB, PRIV, OTH/PRIV, etc.)
 - b. # vaccines administered, by manufacturer, if applicable
 - c. # vaccines administered within the last XX number of days (e.g., 1 day, 7 days, etc.)
 - d. # vaccines administered, disaggregated by age group, sex, race, ethnicity (see example below)
 - e. # vaccines administered, disaggregated by region and/or county
3. Number of individuals who are partially vaccinated
 - a. Disaggregated by age group, sex, race, ethnicity
 - b. By region and/or county
4. Number of individuals who are fully vaccinated
 - a. Disaggregated by age group, sex, race, ethnicity
 - b. By region and/or county
5. Examples of maps:

- a. # doses administered by patient address (shown at county and/or regional level); may show rate instead of # doses at county level
 - b. # doses administered by vaccinating org/facility (shown at county and/or regional level); may show rate instead of # doses at county level
6. COVID-19 vaccine inventory in the state (e.g., # doses received by public health)

The following is an example of the type of information that may be displayed publicly on the TDH website. **Note:** This visualization uses the varicella family vaccine group as an example; this visual is a draft and subject to change.



INITIAL DRAFT